

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier	Reese

Food and Drug Administration

Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration%, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Microbiology Devices Panel of the Medical Devices Advisory Committee

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 11, 2001, from 9:30 a.m. to 6:30 p.m., and October 12, 2001, from 8 a.m. to 5 p.m.

Location: Hilton DC North-Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact: Freddie M. Poole, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-2096, ext. 111, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 125 17. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 11, 2001, the committee will discuss, make recommendations, and vote on a premarket approval application for an in vitro diagnostic device for the determination of endotoxin activity in human whole blood samples. On the same day, the committee will provide advice and recommendations on a premarket notification submission for an in vitro diagnostic

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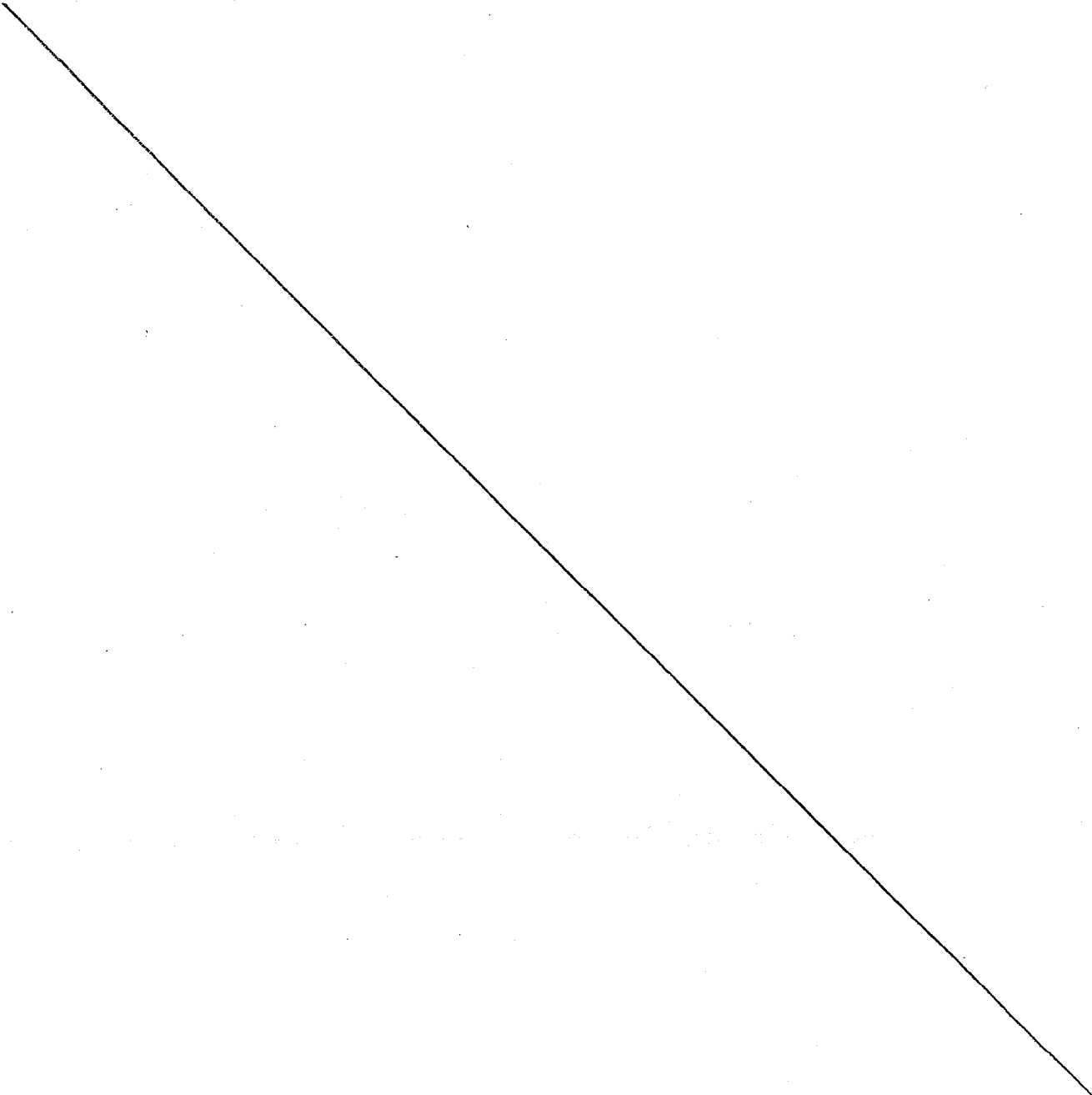
device for detecting and measuring urinary tract infection by semiquantitative analysis of volatile compounds released from a urine sample.

On October 12, 2001, the committee will discuss, make recommendations, and vote on a premarket approval application for an in vitro diagnostic device for measuring the release of gamma-interferon from sensitized lymphocytes in purified protein derivative (PPD)-stimulated whole blood, as an aid in the diagnosis of latent tuberculosis infection. It is intended to aid in the evaluation of individuals who are suspected of having *Mycobacterium tuberculosis* infection or disease, have close contact with infected individuals, or originate from an area where tuberculosis is prevalent.

Background information for each day's topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. Material for the October 11, 2001, session will be posted on October 10, 2001; material for the October 12, 2001, session will be posted on October 11, 2001.

Procedure: On October 11, 2001, from 9:30 a.m. to 6:30 p.m., and on October 12, 2001, from 8:45 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 26, 2001. Oral presentations from the public will be scheduled on October 11, 2001, between approximately 11 a.m. and 11:45 a.m. and 5:30 p.m. and 6 p.m. and on October 12, 2001, between approximately 11 a.m. and 12 noon. and 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 26, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

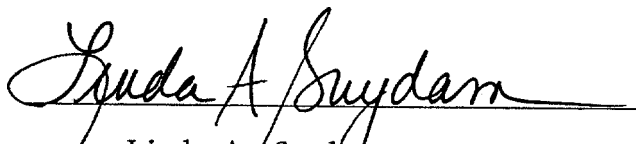
Closed Committee Deliberations: On October 12, 2001, from 8 a.m. to 8:45 a.m., the meeting will be closed to permit FDA staff to present to the committee trade secret and/or confidential



commercial information regarding pending and future device submissions. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

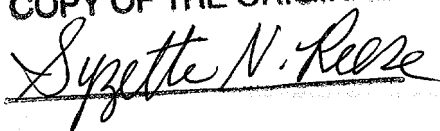
Dated: 9/20/01
September 20, 2001.


Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 'am]

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Syzette N. Reese